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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,491	04/18/2001	Ashit K. Ganguly	IN0931XK	7916

24265 7590 12/13/2002

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER
LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
1623	4

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,491	GANGULY ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The references in the specification are not listed on a proper information disclosure statement. Therefore, unless the references have been cited by the examiner on form PTO-892, applicant should not assume these references have been considered.

Specification

3. The disclosure is objected to because of the following informalities:

Each sentence/paragraph should end in appropriate punctuation including sentences/paragraphs wherein a figure, table, or scheme is incorporated. Items in a list should be separated by appropriate punctuation. See pages 1, 8, 9, 11, 12, 13, 14, 15, 16, 17, 22, 25, 26, 31, 32, 36, 39, 40, 41, 42, 48, 49, 54, 55, 56, 57, 60, 61, and 62. Atoms/bonds in chemical structural formulae should be clearly indicated. See pages 22, 27 (brackets), and 36.

Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-5 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 25; 2 and 30; 3 and 31; 4 and 32; 13; and 4, respectively of copending Application No. 09/837,609 ('609). Although the conflicting claims are not identical, they are not patentably distinct from each.

Claim 1 is drawn to a compound represented by formula (II) wherein at lease one of $R^{2'}$, $R^{3'}$ or $R^{5'}$ is H, R^{20}-$(W)_x$-CO-, R^{20}-$(W)_x$-CS- or R^{20}-$(W)_x$-PO(OH)- and wherein at least one of $R^{2'}$, $R^{3'}$ or R^{5} is not H or a pharmaceutically acceptable salt thereof. Claim 2 is drawn to a pharmaceutical composition of a compound of claim 1 together with a pharmaceutically acceptable carrier.

The '609 application differs from the instantly claimed invention in that '609 is drawn to a compound (pharmaceutical composition) wherein at least one of $R^{2'}$, $R^{3'}$ or $R^{5'}$ is a straight or branched chain polyalkene oxide polymer conjugate. The description

of variables $R^{2'}$, $R^{3'}$ and $R^{5'}$ in the instantly claimed invention is unclear, ambiguous, and confusing as each of the variables have not been clearly defined. Indeed, the claims of the '609 application and the instant invention overlap substantially, for example, when $R^{2'}$ ('609) is a straight or branched chain polyalkene oxide polymer conjugate [not H] and $R^{3'}$ ('609) is H, and to issue a patent to the claims of the instant application could result issuing two patents for the same invention.

Claim 3 is drawn to a method of using a compound represented by formula (II) of claim 1 for treating a susceptible viral infection, wherein the method comprises a therapeutically effective amount of a ribavirin derivative of formula (II) or a pharmaceutically acceptable salt thereof. Claim 4 is drawn to a method of using a compound represented by formula (II) of claim 1 for treating a susceptible viral infection, wherein the method comprises a therapeutically effective amount of a ribavirin derivative of formula (II) or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of an interferon alpha. Claim 5 depends from claim 4 and limits the interferon-alpha to interferon alpha-2a, interferon alpha-2b, a consensus interferon, a purified interferon alpha product or a pegylated interferon-alpha-2a, pegylated interferon-alpha-2b, or pegylated consensus interferon.

The '609 application differs from the instantly claimed invention in that '609 is drawn to a method of treating a patient having chronic hepatitis C infection comprising administering a therapeutically effective amount of a ribavirin derivative wherein at least one of $R^{2'}$, $R^{3'}$ or $R^{5'}$ is a straight or branched chain polyalkene oxide polymer conjugate. The description of variables $R^{2'}$, $R^{3'}$ and $R^{5'}$ in the instantly claimed invention is unclear,

ambiguous, and confusing as each of the variables have not been clearly defined. Indeed, the claims of the '609 application and the instant invention overlap substantially, for example, when $R^{2'}$ ('609) is a straight or branched chain polyalkene oxide polymer conjugate [not H] and $R^{3'}$ ('609) is H, and to issue a patent to the claims of the instant application could result issuing two patents for the same invention.

Claim 15 is drawn to a method of treating patients having chronic hepatitis C infection comprising administering a therapeutically effective amount of ribavirin derivative of formula (I) and a therapeutically effective amount of an interferon alpha for a time period sufficient to eradicate detectable HCV-RNA at the end of said period of administering and to have no detectable HCV-RNA for at least 24 weeks after the end of said period of administrating, and wherein at lease one of $R^{2'}$, $R^{3'}$ or $R^{5'}$ is H, R^{20}-$(W)_x$-CO-, R^{20}-$(W)_x$-CS- or R^{20}-$(W)_x$-PO(OH)- and wherein at least one of $R^{2'}$, $R^{3'}$ or R^5 is not H or a pharmaceutically acceptable salt thereof.

The '609 application differs from the instantly claimed invention in that '609 is drawn to a method of treating patients having chronic hepatitis C infection comprising administering a therapeutically effective amount of ribavirin derivative of formula (I) and a therapeutically effective amount of an interferon alpha wherein at least one of $R^{2'}$, $R^{3'}$ or $R^{5'}$ is a straight or branched chain polyalkene oxide polymer conjugate. The description of variables $R^{2'}$, $R^{3'}$ and $R^{5'}$ in the instantly claimed invention is unclear, ambiguous, and confusing as each of the variables have not been clearly defined. Indeed, the claims of the '609 application and the instant invention overlap substantially, for example, when $R^{2'}$ ('609) is a straight or branched chain polyalkene oxide polymer

conjugate [not H] and $R^{3'}$ ('609) is H, and to issue a patent to the claims of the instant application could result issuing two patents for the same invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13, 15, 16, and 28 of U.S. Patent No. 6,277,830 B1. Although the conflicting claims are not identical, they are not patentably distinct from each.

Claims 1-5 are drawn to compounds/methods as described herein above.

The '830 patent differs from the instantly claimed invention in that '830 is drawn to a compound (pharmaceutical composition) or method of treatment wherein $R^{2'}$ is H, $R^{3'}$ is H, and $R^{5'}$ is $CH_3CH(NH_2)$-CO-, $CH_3CH_2(CH_3)CHCH(NH_2)$-CO- or $H_2N(CH_2)_4CH(NH_2)$-CO-. The description of variables $R^{2'}$, $R^{3'}$ and $R^{5'}$ in the instantly claimed invention is unclear, ambiguous, and confusing as each of the variables have not been clearly defined. Indeed, the claims of the '830 patent and the instant invention overlap substantially, and to issue a patent to the claims of the instant application would be to extend the patent term for the subject matter patented in '520.

Claim Objections

7. Claims 1, 3, 5, and 13 are objected to because of the following informalities: In claim 1, line 13, a space between "," and "$R^{3'}$". Claim 3 contains to periods. A

conjunction is missing in claim 5. In claim 13, the brackets should be replaced by parenthesis in the term "$[CH_3]_2N$". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 11-14, variables $R^{2'}$, $R^{3'}$ and $R^{5'}$ are unclear, ambiguous, and confusing as each of the variables have not been clearly defined. For example, when $R^{2'}$ is R^{20}-$(W)_x$-CO- (not H) the conditions of claim 1 are met; however, $R^{3'}$ and $R^{5'}$ are not defined. The variable "Y" has not been defined (page 97, line 1). The alternate manner in which variables are claimed is unclear, ambiguous, and confusing (page 97, lines 2-3). All claims wherein the variables have not been clearly are indefinite.

Applicant's use of the term "heterocyclic" is unclear as heterocyclic compounds incorporate a heteroatom. Applicant's description of moieties incorporated by the term "heterocyclic" (pages 21-22 of instant specification) is inconsistent with the accepted meaning as a heteroatom may not be part of the ring. The incorporation of said term renders all claims in which they appear indefinite.

Claims 3-5 provide for the use of a compound of formula (II), but, since the claim does not set forth any positive, active steps involved in the method/process, it is unclear

what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 6-7 recite the limitation "interferon-alpha administered" in line 1. There is insufficient antecedent basis for this limitation in the claim. The abbreviations "TIW" and "QOD" have not been defined. The incorporation of said abbreviations renders all claims in which they appear indefinite.

In claims 12-14, it is unclear how moieties representing $R^{5'}$ are attached to the structural core.

In claims 12 and 15, the alternate manner in which variables are claimed is unclear, ambiguous, and confusing (page 99, lines 2-4; page 100, lines 7-8 and 18-20).

In claim 15, the abbreviation "HCV-RNA" has not been defined. The incorporation of said abbreviation renders all claims in which it appears indefinite.

Conclusion

10. Claims 1-17 are pending. Claims 1-17 are rejected. Claims 1-17 appear to be free of the prior art.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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December 11, 2002